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Endoscopy-America, Inc.

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K040476

AUG 26 2004

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.  
600 Corporate Pointe  
Culver City, CA 90230  
(310) 338-8100

Contact: Renate A. MacLaren, Ph.D.  
Senior Regulatory Affairs Specialist

Device Identification: Common Name:  
Extracorporeal Shockwave Lithotripter

Trade Name: Storz Modulith® Lithotripter Model SLX-F2

Indication: The Storz Modulith® Lithotripter Model SLX-F2 is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Device Description: The Storz Modulith® Lithotripter Model SLX-F2 is lithotripsy system comprised of a therapy source, an X-ray system, an ultrasound system and a patient table.

Substantial Equivalence: The Storz Modulith® Lithotripter Model SLX-F2 is substantially equivalent to the Storz Modulith® Lithotripter Model SLX since the basic features, design and intended uses are the same or similar. The minor differences in design, dimensions and features between the Storz Modulith® Lithotripter Model SLX-F2 and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed:

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Renate A. MacLaren, Ph.D.  
Senior Regulatory Affairs Specialist

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 26 2004

Renate A. MacLaren, Ph.D.  
Senior Regulatory Affairs Specialist  
Karl Storz Endoscopy-America, Inc.  
600 Corporate Pointe 5<sup>th</sup> Floor  
CULVER CITY CA 90230-7600

Re: K040476  
Trade/Device Name: Storz MODULITH Model SLX-F2  
Regulation Number: 21 CFR §876.5990  
Regulation Name: Extracorporeal shock wave lithotripter  
Regulatory Class: II  
Product Code: 78 LNS  
Dated: August 11, 2004  
Received: August 12, 2004

Dear Dr. MacLaren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040476

Device Name: Storz MODULITH® Extracorporeal Lithotripter, Model SLX-F2

Indications for Use: The Storz Medical MODULITH® Model SLX F2 is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter..

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

David A. Lynn  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

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